REMARKS

Claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54-55, 58-62 are pending. Claim 61 has been cancelled without prejudice; claims 60 and 62 have been amended; and new claims 63 and 64 have been added. Support for the amendment of claims 60 and 62 may be found in the specification as filed, *inter alia* at page 6, lines 5-15 and page 17, lines 6-8 and page 17, line 20 through page 19, line 12. Support for new claims 63-64 may be found in the specification as filed, *inter alia* at page 6, lines 5-15 and page 17, lines 19 and 22 and page 18, lines 17-18. No new matter has been added. Applicants respectfully request entry of this amendment. Upon entry of the amendment claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54-55, 58-60, and 62-64 will be pending.

Claim of Priority to U.S. 09/204,254, now U.S. Patent No. 6,369,039

The Examiner previously entered Applicant's claim to the benefit of the prior-filed copending nonprovisional application U.S. Ser. No. 09/204,254, filed December 3, 1998 now U.S. Patent No. 6,369,039 B1 ("'039").

However, the Examiner maintains the assertion that applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 because the claims are allegedly unsupported as failing to comply with the written description requirement under 35 U.S.C. § 112, first paragraph.

Applicant respectfully notes that the Examiner misinterpreted a "therapeutic agent" as comprising an angiogenic agent *and* cell cycle inhibitors, when in fact claims 60 and 62 recited that the "therapeutic agent may be selected from the group consisting of an angiogenic agent wherein the angiogenic agent is ...; and cell cycle inhibitors," i.e. selected from the Markush group of an angiogenic agent from the group set forth in the claims or a cell cycle inhibitor. Claim 60 and 62 have been amended to recite all of the various therapeutic agents and various products which may be encoded by the polynucleotide contained in the vector, as fully supported by the specification as filed.

Applicant also respectfully traverses and maintains that the '039 specification provides adequate support for the presently pending claims by explicitly guiding one of skill to *combine* a therapeutic agent and vector in a polymeric coating of at least a portion of a medical device, as claimed in claims 60 and 62 and claims dependent thereon. (Emphasis added)

The original description of the '039 patent provides a specific written description for the numerous combinations of a therapeutic agent and a vector encoding a polypeptide or

protein selected from the above-recited groups, as claimed. (See Col. 4, lines 64-67; Col. 5, lines 1-44; and Col. 5, line 62 through Col. 6, line 7).

Specific guidance is provided by the original '039 specification to combine a therapeutic agent and a vector by the explicit teaching at Col. 5, lines 62-65 of "the **polypeptides or proteins that can be incorporated into the polymer coating 130, or whose DNA can be incorporated,** include without limitation, angiogenic factors..." **... "and combinations thereof" (See Col. 6, lines 7).** Therefore, the '039 specification explicitly teaches that a combination of the claimed elements may be made.

"[[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon '***reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter.***'" *Vas-Cath, Inc. v. Mahurkar* 935 F.2d 1555, 1563 (Fed. Cir. 1991) citing *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d1570, 1575, (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed.Cir. 1983)) (citations omitted) (Emphases added)

Since the '039 specification fully supports a combination of various therapeutic agents and vectors comprising polynucleotides encoding a polypeptide or protein selected from the above-recited group, as claimed, the written description requirement has been complied with. Therefore, the presently pending claims should be entitled to the earlier filing date under 35 U.S.C. § 120. Applicant respectfully requests that such priority be afforded the benefit of the '039 filing date.

Rejection of Claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54, 55 and 58-62 under 35 U.S.C. § 112, First Paragraph - Written Description

The Examiner has rejected claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54, 55, and 58-62 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement by introducing new subject matter into the claimed subject matter.

As noted above, claims 60 and 62 recited a therapeutic agent selected from a Markush group of (1) an angiogenic agent from the group set forth in the claims and (2) a cell cycle inhibitor and a polypeptides and proteins selected from a Markush group of (1) an angiogenic agent from the group set forth in the claims and (2) a cell cycle inhibitor. Claim 60 and 62 have been amended to recite all of the various therapeutic agents and various products which may be encoded by the polynucleotide contained in the vector, as disclosed by the specification as filed. Claim 61 has been cancelled without prejudice.

Applicant respectfully submits that the original specification specifically provides a teaching of a combination of a therapeutic agent selected from the agents recited in claims 60 and 62 and a vector containing a polynucleotide wherein the polynucleotide encodes a protein

or polypeptide selected from the proteins or polypeptides recited in claims 60 and 62. Specifically, the specification as originally filed states:

> The **first therapeutic agent of this invention comprises genetic materials** whereas the **second therapeutic agent of the invention may comprise** either genetic or **non-genetic materials**. The non-genetic material comprises any molecule or compound that induces a beneficial biological or medical reaction in vitro, or in vivo. See Specification, page 17, lines 6-9.

Further page 17, line 20 through page 18, line 16 of the originally filed subject specification provide examples of therapeutic agents and products encoded by the polynucleotides contained in the vector, as presently claimed. (*See* page 17, line 20 and page 16, line 21-22) In addition, page 18, line 17 to page 19, line 12 provide further products which may be encoded by the polynucleotide.

Therefore, *one of skill in the art* would be adequately guided by the specification as originally filed to combine a therapeutic agent selected from the above-recited group and a vector containing a polynucleotide wherein the polynucleotide encodes a protein or polypeptide selected from the above-recited group, as presently claimed in claims 60 and 62 and claims dependent thereon. Accordingly, the presently pending claims fully comply with the written description requirement under 35 U.S.C. § 112, first paragraph. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Rejection of Claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54, 55 and 58-62 under 35 U.S.C. § 112, First Paragraph - Enablement

The Examiner has rejected claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54, 55, and 58-62 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement in the recitation of "and cell cycle inhibitors" for the therapeutic agent and vector components.

As noted above the recitation of "and cell cycle inhibitors" was part of a Markush group for the therapeutic agents and the products reciting "angiogenic agents" and "cell cycle inhibitors", i.e. either may be selected. Applicant has amended claims 60 and 62 to recite the therapeutic agents and products encoded by a polynucleotide contained within a vector which are enabled by the subject specification as filed. Claim 61 has been cancelled without prejudice. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Rejection of claims 60-62 under 35 U.S.C. § 112, Second Paragraph

The Examiner has maintained the rejection of claim 50 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. The Examiner opines that the term "combination thereof" is a relative term and that the metes and bounds are not defined because the claims do not define what combination is being claimed.

Without conceding the correctness of the Examiner's position, applicant has amended claims 60 and 62 to recite a therapeutic agent and a vector containing a polynucleotide to specify that this combination is being claimed. Applicant respectfully requests reconsideration and withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Respectfully submitted,
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Date

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